

PSJ3

Exhibit 451

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**From:** Ducca, Anita  
**Sent:** Monday, October 31, 2016 4:10 PM  
**To:** 'Patrick M. Kelly (pkelly@hda.org)'  
**Subject:** Chronology of HDMA DEA involvement updated 10-31-16.pptx  
**Attachments:** Chronology of HDMA DEA involvement updated 10-31-16.pptx

Hi, Patrick, per your request, attached is the chronology of interactions with DEA. It focuses mostly on meetings we had with them and includes an occasional "one off" clarification request that we've had, but not our usual rulemaking comment letters.

Please look especially at slides #11 and 12 to see if you can think of anything else. (#13 has the DMC-specific speaking events)

Also, on slide 11, if I recall correctly, you or maybe John G, sent a letter to either Lou or to Chuck asking for a speaker at DMC. I don't have the letter or the date. Do you?

Finally, Michelle Leslie asked for a list of when DEA spoke. Perry is asking her to put together something similar but I think this should do it for both.

Anita

# Chronology of HDMA Involvement in DEA Controlled Substances and Suspicious Orders

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Date	Activity
~ 2005	DEA begins wholesale distributor “Meetings”
9/27/06 2/7/07 12/27/07	DEA sends letters on “ <i>responsibilities of controlled substances distributors</i> ” for reporting and preventing diversion to distributors
2007	DEA suspends several wholesale distributor licenses
7/25/07	HDMA requests meeting with J. Rannazzisi , Deputy Assistant Administrator, Office of Diversion Control, DEA
9/07/07	HDMA (S. Melville, A. Ducca, D. Durkin) meets w DEA on “Effective Controls Against Diversion of Controlled Substances” (M. Caverly, M. Mapes)
10/16/07	HDMA’s DEA Planning meeting with the RAC; Kyle Wright (DEA) invited and gives SO monitoring presentation
10/16 & 12/19/07	Planning meeting participant and Counsel recommendations to develop a “guidance.”

# DEA Chronology (Continued)

Date	Activity
1/3/08	HDMA launches ICG development
2/22/08	GPPC & ExComm reviews/approves draft ICG & DEA strategy
4/15, 6/6 & 9/5/08	Meetings w DEA's Chief Counsel's Office to present, review, finalize ICG. Request DEA's "endorsement"
7/17/08	HDMA & DEA meeting. HDMA states: customers setting up accounts with several distributors. Is DEA aware? Is DEA evaluating? DEA: "yes"
10/17/08	DEA letter on the ICG: "...commends ...HDMA... in its efforts to assist its membership to fulfill their [CSA] obligations...". HDMA releases final ICG.
11/14/08	HDMA ICG Webinar for HDMA members
2/24/09	"Educational" meeting between DEA and HDMA. Verbal request for ARCOS data. (16 DEA attendees; HDMA: A. Ducca, D. Durkin, S. Mays, D. Walker, J. Lumpkin, B. Giacalone )
Spring 2010	Press reports of another wholesale distributor registration suspension
7/8/10	HDMA letter to Act. Admin. Leonhart requesting ARCOS data, & other info

# DEA Chronology (Continued)

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Date	Activity
9/30/10	HDMA meets with GAO representatives to input on their DEA study. GAO Report available at: <a href="http://www.gao.gov/products/GAO-11-744">http://www.gao.gov/products/GAO-11-744</a>
10/15/10	S. Melville e-mail to M. Caverly requesting status of July 8 ARCOS letter
10/19/10	HDMA letter to M. Leonhart requesting a meeting
11/10/10	DEA notifies HDMA that the meeting has been delegated to J. Rannazzisi
12/07/10	HDMA meets with M. Caverly, & other DEA staff (J. Rannazzisi was "called away"); HDMA recommends: SO monitoring clarifications; update of DEA's letters to distributors & more
02/16/11	GPPC Directive: No HDMA organized ARCOS or other customer review; but, HDMA should conduct Hill educational meetings
02/25/11	ExComm concurs with GPPC directive. Requests review of consistency between the ICG and member practices. Is ICG "current?"
03/01/11	Regulatory Affairs Committee meeting - develop compliance questions
~ 03/11	Press reports of another wholesale distributor registration suspension.

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# DEA Chronology (Continued)

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Date	Activity
06/01/11	HDMA sends to M. Leonhart 12 pages of SO compliance questions and a summary of the 12/07/10 meeting as follow-up
06/05/11	ExComm discusses ICG review (still current but could use updating); reconsider ICG reissuance after GAO rept release and we receive DEA's answers to our questions
06/10/11	C. Gallagher call to A. Ducca. DEA would not give "certainty" by answering many of the questions. Further, DEA will not "be giving a check list" of steps that, if performed, will give certainty [that they're in compliance]
11/08/11	HDMA requests meeting with DEA (J. Partridge and B. Boockholdt) and "3-4 members of our Regulatory Affairs Committee"
11/16/11	C. Gallagher response: "... [DEA] would prefer to ... meet... only HDMA staff and not with members like we have done in the past." [AD note: Incorrect. HDMA and members <u>have</u> met jointly at DEA –HDMA meetings in the past.]
11/21/11	C. Gallagher asks what is HDMA's Outside Counsel's role at such a meeting; states others in DEA will ask



# DEA Chronology (Continued)

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Date	Activity
11/22/11	A. Ducca reply to C. Gallagher's Outside Counsel role question
12/19/11	HDMA- DEA meeting; DEA states: HDMA members aren't looking at and acting properly on ARCOS data
02/03 & 02/04/12	DEA issues Cardinal ISO; followed by 2 CVS ISOs
Spring 2012	Court and related proceedings for above DEA ISOs/actions
03/01/12	J. Gray testifies at House E & C Subcommittee on Commerce, Manufacturing and Trade hearing. Former Chairwoman Mary Bono Mack (R-CA). (HDMA also answered follow-up questions after the hearing)
04/13/12	HDMA meets with W&C (Barnett and Cooper) on DEA strategic options
04/20/12	J. Gray sends memo to ExComm summarizing DEA strategic options
05/03/12	Sen. C. Grassley (IA) and Sen. S. Whitehouse (RI) request that GAO study the impact of DEA's policies and regulations on "the growing drug shortage crisis...[of] controlled substances..."

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# DEA Chronology (Continued)

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Date	Activity
05/07/12	Sen. Chuck Grassley (IA) and Sen. Sheldon Whitehouse (RI) issue a press release on their request for the GAO to study DEA's possible contribution to controlled substances shortages. (Quotas & emergency patients' drugs)
05/09/12	HDMA files Amicus Brief with the US District Court of Appeals for the DC Circuit supporting Cardinal
06/10/12	Board discusses potential DEA actions
06/26/12	The WV Attorney General announced lawsuits against 14 pharmaceutical drug distributors, alleging negligent practices helped fuel the state's abuse epidemic
07/03/12	A. Ducca sends e-mail to C. Gallagher of DEA asking the status of answers to HDMA's questions from 06/01/11
07/05/12	C. Gallagher responds that she will look into the questions' status.
08/30/12	RAC discussion of "Regulatory Options" for addressing DEA issues; recommends petition for new SO monitoring rule but does not recommend other actions

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# DEA Chronology (Continued)

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Date	Activity
09/18/12	GPPC discusses Regulatory Options; says: wait for PR [APCO] approach
Early Dec. 2012	A. Ducca and C. Gallagher discuss meeting requests. [an HDMA-DEA meeting with HDMA members; DMC] C. Gallagher indicates she wishes to “turn back to” the HDMA questions [that were submitted to DEA 06/01/11]
Early Dec. 2012 thru Spring 2013	Numerous e-mails and calls, requesting, repeating and reminding C. Gallagher of the meeting requests. [See separate insert]
01/13	Shortly after DEA proposed the disposal/take back rule, [77 Fed. Reg. 75783 (Dec. 21, 2012)] HDMA requested that a DEA representative participate in a conference call on the rule, mostly to answer questions. DEA declined. <i>[Note, there are no legal or rulemaking restriction on regulatory agency communications about a proposed rule while it is open for public comment.]</i>
03/15/13	RAC updates potential “Regulatory Options”. New suggestion for a potential legal journal article included.
4/29/13	Letter from J. Gray to A. Santos; DMC thank you and reiterates our request for an HDMA-DEA meeting sometime in 2013.

# DEA Chronology (Continued)

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Date	Activity
5/17/13	C. Gallagher voice mail - DEA has agreed to meet HDMA. (In subsequent conversations, unclear whether DEA is will include HDMA members in the meeting. C. Gallagher agrees to ask senior leadership if acceptable.)
5/24/13	Received e-mail from C. Gallagher that "DEA will definitely be able to speak at HDMA's 2014 [DMC] Conference."
6/6 & 6/7 2013	DEA and HDMA set meeting date of 7/31/13
7/3/13	HDMA submits to DEA HDMA's questions for discussion at the 7/31 meeting
7/29/13	DEA cancels the 7/31 meeting. E-mail from C Gallagher states: "I am still waiting on confirmation from OD for us to meet. In the mean time, Barbara Boockholdt has scheduling conflict and cannot meet on Wed and many of the issues are handled by her Section. At this rate, I don't think we should meet this week."

# DEA Chronology (Continued)

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Date	Activity
11/26/13	E-mail to C. Gallagher asking if she reviewed the letter about ARCOS error corrections. Also reminded her that DEA had agreed to speak at DMC 2014, asking if the recommended time slot would be workable for DEA's speaker.
1/15/14 2/7/14	Reminders to C. Gallagher of DEA that the agency had agreed to speak at the 2014 DMC and requested the speaker's name and contact information.
2/11/14	Received e-mail from C. Gallagher stating that DEA "...is not able to present at the conference..." [In other words, will not speak at DMC after all.]
3/7/14	Discussed ARCOS error correction requirement with John Partridge, Exec. Assistant to the DEA Deputy Administration in ODC. Mr. Partridge indicated that DEA would revert to the normal reporting time frames. (Described in A. Ducca e-mail to RAC 3/7/14.)
11/1/13	HDMA submits letter to DEA requesting clarification/revision of a recent directive to speed submission of ARCOS error corrections. (Included notation that many/most errors were related to errors on DEA's system, not due to actual reporting errors.)

# DEA Chronology (Continued)

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Date	Activity
1/15/14 2/7/14	Reminders to C. Gallagher of DEA that the agency had agreed to speak at the 2014 DMC and requested the speaker's name and contact information.
2/11/14	Received e-mail from C. Gallagher stating that DEA "...is not able to present at the conference..."
3/7/14	Discussed ARCOS error correction requirement with John Partridge, Exec. Assistant to the DEA Deputy Administration in ODC. Mr. Partridge indicated that DEA would revert to the normal reporting time frames. (Described in A. Ducca e-mail to RAC 3/7/14.)
11/1/13	HDMA submits letter to DEA requesting clarification/revision of a recent directive to speed submission of ARCOS error corrections. (Included notation that many/most errors were related to errors on DEA's system, not due to actual reporting errors.)
3/7/14	Anita Ducca discussed ARCOS error correction requirement with John Partridge, Exec. Assistant to the DEA Deputy Administration in ODC. Mr. Partridge indicated that DEA would revert to the normal reporting time frames. (Described in A. Ducca e-mail to RAC 3/7/14.)

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# DEA Chronology (Continued)

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Date	Activity
7/28/14	HDMA sent a letter to DEA regarding the final rule placing Tramadol products into Schedule IV. The letter requested that distributors be allowed to sell existing inventory or to continue to sell them for 180 days after the effective date
8/19/14	Date of DEA response to HDMA denying request to be able to continue to sell existing Tramadol inventory
10/15	Various communications between John Gray and Chuck Rosenberg and between John Gray and Lou Milione. Rosenberg and Milione indicated to John G a willingness to reestablish relationships with HDMA. They indicated that DEA would hold a meeting to discuss DEA's leadership change and new directions early in the year and invited John G. John G. invited Lou M. to speak at DMC
2/29/16	DEA holds Trade Association Meeting to introduce HDMA and others (e.g., NACDS, APhA, PhRMA) to DEA's new senior leadership team (Chuck Rosenberg, Lou Milione and section chiefs); discuss upcoming initiatives; receive input from industry; rebuild relationships
????	HDMA sends a letter to Lou Milione (or to Chuck R?) requesting a DEA speaker for DMC

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Date	Activity
3/7/16	Lou Milione is keynote speaker at HDMA's DMC. Demetra Ashley (Lou M's Deputy) and Lou M. conduct DMC breakout session. Demetra discussed regeneration of DEA's Wholesale Distributor Initiative
6/12/16	Lou Milione, Deputy Assistant Administrator, Office of Diversion Control, Guest Speaker at HDMA/HDA's Board meeting at BLC

Updated 10-31-16 by Anita Ducca

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# DEA Chronology – DMC Participation

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Date	DMC Speakers from DEA
2008	Mark Caverly, <i>Chief, Liaison and Policy Section, Office of Diversion Control (ODC)</i>
2009	Mark Caverly, <i>Chief, Liaison and Policy Section, ODC</i>
2010	Mark Caverly, <i>Chief, Liaison and Policy Section, ODC</i>
2011	Cathy Gallagher, <i>Acting Chief, Liaison and Policy Section, ODC</i>
2012	John Partridge, <i>Chief, Liaison and Policy Section, ODC</i>
2013	Alan G. Santos, <i>Associate Deputy Assistant Administrator, ODC</i>
2014 2015	IN 2014, DEA retracted its earlier commitment to speak at DMC in 2014. DEA, therefore, did not speak at DMC in 2014 (or in 2015).
2016	Lou Milione, <i>Deputy Assistant Administrator, ODC</i> (Keynote address); Demetra Ashley, <i>Associate Deputy Assistant Administrator, ODC</i> (Breakout session, with Lou M also participating/answering questions)

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